Purdue Pharma L.P. et al. v. Accord Healthcare Inc.
C.A. No. 20-1362 (RGA) (JLH)

EXHIBIT 2P

PLAINTIFFS' STATEMENT OF ISSUES OF FACT THAT REMAIN TO BE LITIGATED

Pursuant to D. Del. LR 16.3(c)(4), Plaintiffs hereby submit the following Statement of Issues of Fact That Remain to Be Litigated. This statement is not intended to be exhaustive, and, in addition to what is set forth herein, Plaintiffs reserve the right to prove any matters identified in the pleadings, fact and expert discovery, and any of the accompanying statements of facts and legal issues to be litigated at trial. Plaintiffs reserve the right to disprove, prove a fact contrary to, or prove the opposite of any issue of fact identified in Defendant's Proposed Findings of Fact.

To the extent Plaintiffs' Statement of Issues of Law That Remain to Be Litigated contains issues of fact, those issues are incorporated herein by reference. If the Court determines that any issue identified in this list as an issue of fact is more properly considered an issue of law, Plaintiffs incorporate such issues by reference into their Statement of Issues of Law That Remain to Be Litigated. By including a fact herein, Plaintiffs do not assume the burden of proof or production with regard to that fact.

Plaintiffs' identification of the issues of fact that remain to be litigated is based in part on their current understanding of the arguments Defendant is likely to make in support of its invalidity defenses. To the extent Defendant attempts to introduce different or additional facts to meet its burden of proof, Plaintiffs reserve the right to object to and/or contest those facts, and to present any and all rebuttal evidence in response to those facts.

I. VALIDITY OF THE LOW 8α/ABUK PATENTS-IN-SUIT

A. Priority Date

1. Whether Plaintiffs have proven that the asserted claims of the Low 8α/ABUK

patents[1] are entitled to a priority date earlier than the effective filing date of U.S. Provisional Application No. 60/557,492 on March 30, 2004.

2. [redacted]

B. Collateral Estoppel

3. Whether Defendant has proven by clear and convincing evidence that Plaintiffs are collaterally estopped from contesting any findings of fact from a previous litigation (*In re OxyContin Antitrust Litig.*, 994 F. Supp. 2d 367 (S.D.N.Y. 2014)) concerning different patents in the same family as the Low 8α/ABUK patents.

4. Whether Defendant has proven by clear and convincing evidence that the validity issues relevant to the asserted claims of the Low 8α/ABUK patents are substantially identical to validity issues adjudicated during litigation concerning different patents in the same family as the Low 8α/ABUK patents.

5. Whether Defendant has proven by clear and convincing evidence that the findings of fact from a previous litigation concerning different patents in the same family as the Low 8α/ABUK patents that it seeks to rely on in this case were essential to the judgment in the prior litigation.

6. Whether Defendant has proven by clear and convincing evidence that the findings of fact from a previous litigation concerning different patents in the same family as the Low 8α/ABUK patents that it seeks to rely on in this case were actually litigated.

[1] The asserted claims of the Low 8α/ABUK patents are as follows: 933 patent claims 3 and 11; 919 patent claims 21 and 24; and 434 patent claim 20.

C. Previously Decided Issues Pertaining to the Low 8α/ABUK Patents

Plaintiffs intend to prove the following facts previously decided in litigation:

7. "[T]he prior art never identified" 8α. *In re OxyContin Antitrust Litig.*, 994 F. Supp. 2d 367, 397 (S.D.N.Y. 2014).

8. "[P]rior art did not disclose the existence of 8α or teach that it converts to 14-hydroxy. *Id.*

9. The "very existence [of 8α] was unexpected." *Id.* at 401.

10. "[I]dentifying 8α was genuine insight." *Id*.

11. "[T]he prior art did not disclose oxycodone API substantially free of 14-hydroxy." *Id.* at 413.

12. "Prior art that disclosed oxycodone API did not disclose oxycodone API substantially free of 14-hydroxy." *Id.* at 398.

13. "Figure 2 [of the '933 specification] teaches that 8α can undergo acid-catalyzed dehydration to form 14-hydroxy." *Id.* at 397.

14. "[T]rial evidence revealed that prior art OxyContin had levels of 14-hydroxy at rates greater than 800 ppm." *Id.* at 398.

15. The district court addressing the validity of certain claims in the '799, '800, and '072 patents, which are in the same family as the Low 8α/ABUK patents, considered "only the product limitations of [the asserted claims], not process limitations or source limitations." *Id.* at 403. Therefore, 8α was irrelevant to the validity of the asserted claims.

16. The district court addressing the validity of '799, '800, and '072 patent claims assessed validity of "the low-ABUK oxycodone API product—and its various purity and oral dosage form limitations—not oxycodone API with 14-hydroxy obtained from 8α." *Id.* at 403.

17. The district court addressing the validity of '799, '800, and '072 patent claims found that, "[a]s a matter of law, the 8α-derived limitation of the asserted product claims is disregarded as a process limitation." *Id.* at 405.

18. The district court addressing the validity of '799, '800, and '072 patent claims held that, "with its knowledge of 8α Purdue had the capability to practice its claims in a way that would have been nonobvious." *Id.* at 407.

19. "Proksa does not … teach the existence of 8α." *Id.* at 395.

20. "Chiu, for example, disclosed a method for preparing low-ABUK oxycodone free base, but that reference did not teach how to convert its low-ABUK free base into a low-ABUK salt and does not each the preparation of oxycodone hydrochloride API." *Id.* at 398.

21. "Each [of the '799, '800, and '072] patent[s] includes Figure 1, which illustrates the claimed synthetic scheme—including the creation of 8α as a byproduct of the oxidation of thebaine." *Id.* at 409.

22. "Figure 2 discloses that 8α will dehydrate to form 14–hydroxy in the presence of acid." *Id.*

23. The district court "credit[ed] Wuest's testimony" that "Example 3 of the specification demonstrates to a skilled artisan conditions that convert 8α into 14–hydroxy" and that "a skilled artisan would understand that the 8β compound is essentially inert under these conditions and would not undergo this acid-induced transformation." *Id.* at 409-10 (internal quotations omitted).

24. "Wuest credibly opines that an ordinary skilled artisan would know that the 8,14-dihydroxy reacting in [the conditions of Example 3] *must* be 8α and not 8β, because the Weiss reference shows that 8β is inert in such conditions." *Id.* at 390 (emphasis in original).

25. "As Wuest explains, Weiss shows 8β reacting in 6N hydrochloride ('HCl') and not reacting in 2N HCl. An ordinarily skilled chemist would understand that 6N HCl is more concentrated than 2N HCl, which in turn is more concentrated than 0.2N HCl [used in Example 3], and that an acid-catalyzed reaction that occurs in 6N HCl but not in 2N HCl will not occur in 0.2N HCl." *Id.* at 390-391 (citations omitted).

26. "On balance, Wuest's credible explanation of the Weiss reference, balanced against Teva's attacks on that explanation, persuades the Court that a person of ordinary skill in the art would have read Example 3 as describing 8α." *Id.* at 391.

D. Obviousness

27. Whether Defendant has proven by clear and convincing evidence that the asserted claims of the Low 8α/ABUK patents (except for claim 24 of the 919 patent addressed in the following paragraph) would have been obvious to a POSA at the time of the inventions based on the prior art, in particular, Chiu, Lin and Ramanathan in view of the knowledge of a POSA (including Proska and Weiss).

28. Whether Defendant has proven by clear and convincing evidence that claim 24 of the 919 patent would have been obvious to a POSA at the time of the inventions based on the prior art, in particular, Chiu, Lin, Ramanathan and McGinity in view of the knowledge of a POSA (including Proska and Weiss).

29. Whether Defendant has proven by clear and convincing evidence that, as of their priority date, the inventions of the asserted claims of the Low 8α/ABUK patents would have been obvious to a POSA, in light of the scope and content of the prior art, the differences between each claim at issue and the prior art, the level of ordinary skill at that time, and objective indicia of non-obviousness, in light of Defendant's above-identified prior art combinations.

30. Whether Defendant has proven by clear and convincing evidence that either of its prior art combinations disclose all of the elements of the corresponding asserted claims of the Low 8α/ABUK patents. For example, whether the inventors of the Low 8α/ABUK patents were the first to identify that the oxidation of thebaine in accordance with Figure 1 produced 8α.

31. Whether Defendant has proven by clear and convincing evidence that a POSA as of the priority date would have started with or selected Defendant's prior art and the particular disclosures therein when attempting to achieve the inventions of the asserted claims of the Low 8α/ABUK patents.

32. Whether Defendant has proven by clear and convincing evidence that, at the time of the inventions of the asserted claims of the Low 8α/ABUK patents, a POSA would have had a motivation to combine particular teachings of the selected alleged prior art in a way that practices the inventions of the asserted claims of the Low 8α/ABUK patents.

33. Whether Defendant has proven by clear and convincing evidence that, at the time of the inventions of the asserted claims of the Low 8α/ABUK patents, a POSA would have had a motivation to reduce the levels of 14-hydroxy in oxycodone compositions, or otherwise develop the inventions of the asserted claims of the Low 8α/ABUK patents, based on certain confidential FDA communications that are not prior art.

34. Whether Defendant has proven by clear and convincing evidence that, at the time of the inventions of the asserted claims of the Low 8α/ABUK patents, certain confidential FDA communications were publicly available or otherwise known to the POSA.

35. Whether Defendant has proven by clear and convincing evidence that a POSA would have had a reasonable expectation of success of achieving the inventions of the asserted claims of the Low 8α/ABUK patents.

36. Whether the prior art as a whole taught a POSA away from the inventions of the asserted claims of the Low 8α/ABUK patents.

37. Whether a POSA would have understood the reference to "8,14-dihydroxy-7,8-dihdrocodeinone" in Example 3 of the Low 8α/ABUK patents as referring to 8α and not 8β, particularly in view of Weiss that teaches that 8β does not convert under even more aggressive conditions than those disclosed in Example 3.

1. Chiu

To the extent they are required to do so, Plaintiffs intend to prove the following facts concerning Chiu:

38. Chiu does not disclose the conversion of oxycodone base into oxycodone salt.

39. Chiu does not disclose the limit of detection for 14-hydroxycodeinone by any analytical method available at the time of the disclosure.

40. Chiu does not disclose the levels of 14-hydroxycodeinone in the oxycodone base made according to its disclosures and does not disclose an oxycodone base or salt with less than 100 ppm of 14-hydroxycodeinone.

41. Chiu does not disclose, teach or suggest 8,14-dihydroxy-7,8-dihydrocodeinone, let alone its 8α isomer.

42. Chiu does not disclose, teach or suggest dehydration of 8,14-dihydroxy-7,8-dihydrocodeinone, let alone 8α.

43. Chiu does not disclose a limit of detection for residual 14-hydroxycodeinone.

44. Chiu does not disclose oxycodone hydrochloride, let alone how to produce an oxycodone salt with less than 25 ppm or 100 ppm of 14-hydroxycodeinone.

45. Chiu does not disclose oxycodone salt with 14-hydroxycodeinone levels less than

25 ppm or 100 ppm.

46. Chiu does not disclose, teach or suggest oxycodone hydrochloride consisting of 95% oxycodone hydrochloride, 8α, and less than 25 ppm of 14-hydroxycodeinone.

47. Chiu does not disclose, teach or suggest oxycodone hydrochloride compositions or pharmaceutical formulations having 8α, let alone a ratio of 8α to oxycodone hydrochloride of 0.04% or less.

48. Chiu does not disclose, teach or suggest oxycodone hydrochloride compositions or pharmaceutical formulations consisting of oxycodone hydrochloride, 8α, and a ratio of 8α to oxycodone hydrochloride of 0.04% or less.

49. Chiu does not disclose, teach or suggest oxycodone hydrochloride compositions or pharmaceutical formulations consisting of oxycodone hydrochloride, 8α, less than 100 ppm of 14-hydroxycodeinone, and a ratio of 8α to oxycodone hydrochloride of 0.04% or less.

50. Chiu does not disclose, teach or suggest a process for preparing an oxycodone hydrochloride composition having less than 25 ppm oxycodone hydrochloride, comprising removing 8α,14-dihydroxy-7,8-dihydrocodeinone from an oxycodone base composition and converting the oxycodone base composition to an oxycodone hydrochloride composition having less than 25 ppm of 14-hydroxycodeinone.

51. Chiu does not disclose, teach or suggest a purified oxycodone base or HCl salt thereof, or a process for making such oxycodone that contains 8α,14-dihydroxy-7,8-dihydrocodeinone or salt thereof, which comprises (i) reducing the amount of 8α,14-dihydroxy-7,8-dihydrocodeinone or salt thereof in the oxycodone base or oxycodone HCl, (ii) dissolving the resultant oxycodone from step (i) in a suitable recrystallization solvent; (iii) cooling the recrystallization solvent to precipitate purified oxycodone base or HCl salt thereof, and (iv)

recovering the purified oxycodone.

52. Chiu was considered by the PTO Examiner in allowing the asserted claims of the Low 8α/ABUK patents.

2. Lin

To the extent they are required to do so, Plaintiffs intend to prove the following facts concerning Lin:

53. Lin is not prior art.

54. Lin does not disclose, teach or suggest oxycodone salt with less than 100 ppm of 14-hydroxycodeinone.

55. Lin does not disclose, teach or suggest 8α.

56. Lin does not disclose, teach or suggest oxycodone hydrochloride consisting of 95% oxycodone hydrochloride, 8α, and less than 25 ppm of 14-hydroxycodeinone.

57. Lin does not disclose, teach or suggest oxycodone hydrochloride compositions or pharmaceutical formulations having 8α, let alone a ratio of 8α to oxycodone hydrochloride of 0.04% or less.

58. Lin does not disclose, teach or suggest oxycodone hydrochloride compositions or pharmaceutical formulations consisting of oxycodone hydrochloride, 8α, and a ratio of 8α to oxycodone hydrochloride of 0.04% or less.

59. Lin does not disclose, teach or suggest oxycodone hydrochloride compositions or pharmaceutical formulations consisting of oxycodone hydrochloride, 8α, less than 100 ppm of 14-hydroxycodeinone, and a ratio of 8α to oxycodone hydrochloride of 0.04% or less.

60. Lin does not disclose dehydration of 8,14-dihydroxy-7,8-dihydrocodeinone, let alone 8α.

61. Lin does not disclose, teach or suggest a process for preparing an oxycodone hydrochloride composition having less than 25 ppm oxycodone hydrochloride, comprising removing 8α,14-dihydroxy-7,8-dihydrocodeinone from an oxycodone base composition and converting the oxycodone base composition to an oxycodone hydrochloride composition having less than 25 ppm of 14-hydroxycodeinone.

62. Lin does not disclose, teach or suggest a purified oxycodone base or HCl salt thereof, or a process for making such oxycodone that contains 8α,14-dihydroxy-7,8-dihydrocodeinone or salt thereof, which comprises (i) reducing the amount of 8α,14-dihydroxy-7,8-dihydrocodeinone or salt thereof in the oxycodone base or oxycodone HCl, (ii) dissolving the resultant oxycodone from step (i) in a suitable recrystallization solvent; (iii) cooling the recrystallization solvent to precipitate purified oxycodone base or HCl salt thereof, and (iv) recovering the purified oxycodone.

63. Lin was considered by the PTO Examiner in allowing the asserted claims of the Low 8α/ABUK patents.

3. Ramanathan

To the extent they are required to do so, Plaintiffs intend to prove the following facts concerning Ramanathan:

64. Ramanathan does not disclose, teach or suggest oxycodone salt with less than 100 ppm of 14-hydroxycodeinone.

65. Ramanathan does not disclose, teach or suggest 8α.

66. Ramanathan does not disclose, teach or suggest oxycodone hydrochloride consisting of 95% oxycodone hydrochloride, 8α, and less than 25 ppm of 14-hydroxycodeinone.

67. Ramanathan does not disclose, teach or suggest oxycodone hydrochloride

compositions or pharmaceutical formulations having 8α, let alone a ratio of 8α to oxycodone hydrochloride of 0.04% or less.

68. Ramanathan does not disclose, teach or suggest oxycodone hydrochloride compositions or pharmaceutical formulations consisting of oxycodone hydrochloride, 8α, and a ratio of 8α to oxycodone hydrochloride of 0.04% or less.

69. Ramanathan does not disclose, teach or suggest oxycodone hydrochloride compositions or pharmaceutical formulations consisting of oxycodone hydrochloride, 8α, less than 100 ppm of 14-hydroxycodeinone, and a ratio of 8α to oxycodone hydrochloride of 0.04% or less.

70. Ramanathan does not disclose dehydration of 8,14-dihydroxy-7,8-dihydrocodeinone, let alone 8α.

71. Ramanathan does not disclose, teach or suggest a process for preparing an oxycodone hydrochloride composition having less than 25 ppm oxycodone hydrochloride, comprising removing 8α,14-dihydroxy-7,8-dihydrocodeinone from an oxycodone base composition and converting the oxycodone base composition to an oxycodone hydrochloride composition having less than 25 ppm of 14-hydroxycodeinone.

72. Ramanathan does not disclose, teach or suggest a purified oxycodone base or HCl salt thereof, or a process for making such oxycodone that contains 8α,14-dihydroxy-7,8-dihydrocodeinone or salt thereof, which comprises (i) reducing the amount of 8α,14-dihydroxy-7,8-dihydrocodeinone or salt thereof in the oxycodone base or oxycodone HCl, (ii) dissolving the resultant oxycodone from step (i) in a suitable recrystallization solvent; (iii) cooling the recrystallization solvent to precipitate purified oxycodone base or HCl salt thereof, and (iv) recovering the purified oxycodone.

73. Ramanathan was considered by the PTO Examiner in allowing the asserted claims

of the Low 8α/ABUK patents.

4. Proksa

To the extent they are required to do so, Plaintiffs intend to prove the following facts concerning Proksa

74. Proksa does not disclose, teach or suggest oxycodone base or oxycodone salt, let alone an oxycodone base or salt with less than 100 ppm of 14-hydroxycodeinone.

75. Proksa does not disclose, teach or suggest oxycodone hydrochloride consisting of 95% oxycodone hydrochloride, 8α, and less than 25 ppm of 14-hydroxycodeinone.

76. Proksa does not disclose, teach or suggest oxycodone hydrochloride compositions or pharmaceutical formulations having 8α, let alone a ratio of 8α to oxycodone hydrochloride of 0.04% or less.

77. Proksa does not disclose, teach or suggest oxycodone hydrochloride compositions or pharmaceutical formulations consisting of oxycodone hydrochloride, 8α, and a ratio of 8α to oxycodone hydrochloride of 0.04% or less.

78. Proksa does not disclose, teach or suggest oxycodone hydrochloride compositions or pharmaceutical formulations consisting of oxycodone hydrochloride, 8α, less than 100 ppm of 14-hydroxycodeinone, and a ratio of 8α to oxycodone hydrochloride of 0.04% or less.

79. Proksa neither discloses nor suggests the precise mechanism for the acid-induced hydration postulated in Proksa

80. Proksa was considered by the PTO Examiner in allowing the asserted claims of the Low 8α/ABUK patents.

5. Weiss

To the extent they are required to do so, Plaintiffs intend to prove the following facts concerning Weiss:

81. Weiss does not disclose, teach or suggest 8α.

82. Weiss does not disclose, teach or suggest oxycodone base or oxycodone salt, let alone an oxycodone base or salt with less than 100 ppm of 14-hydroxycodeinone.

83. Weiss does not disclose, teach or suggest oxycodone hydrochloride consisting of 95% oxycodone hydrochloride, 8α, and less than 25 ppm of 14-hydroxycodeinone.

84. Weiss does not disclose, teach or suggest oxycodone hydrochloride compositions or pharmaceutical formulations having 8α, let alone a ratio of 8α to oxycodone hydrochloride of 0.04% or less.

85. Weiss does not disclose, teach or suggest oxycodone hydrochloride compositions or pharmaceutical formulations consisting of oxycodone hydrochloride, 8α, and a ratio of 8α to oxycodone hydrochloride of 0.04% or less.

86. Weiss does not disclose, teach or suggest oxycodone hydrochloride compositions or pharmaceutical formulations consisting of oxycodone hydrochloride, 8α, less than 100 ppm of 14-hydroxycodeinone, and a ratio of 8α to oxycodone hydrochloride of 0.04% or less.

87. Weiss was considered by the PTO Examiner in allowing the asserted claims of the Low 8α/ABUK patents.

6. McGinity

To the extent they are required to do so, Plaintiffs intend to prove the following facts concerning McGinity:

88. McGinity does not disclose, teach or suggest 8α.

89. McGinity does not disclose, teach or suggest oxycodone base or oxycodone salt, let alone an oxycodone base or salt with less than 100 ppm of 14-hydroxycodeinone.

90. McGinity does not disclose, teach or suggest oxycodone hydrochloride consisting of 95% oxycodone hydrochloride, 8α, and less than 25 ppm of 14-hydroxycodeinone.

91. McGinity does not disclose, teach or suggest oxycodone hydrochloride compositions or pharmaceutical formulations having 8α, let alone a ratio of 8α to oxycodone hydrochloride of 0.04% or less.

92. McGinity does not disclose, teach or suggest oxycodone hydrochloride compositions or pharmaceutical formulations consisting of oxycodone hydrochloride, 8α, and a ratio of 8α to oxycodone hydrochloride of 0.04% or less.

93. McGinity does not disclose, teach or suggest oxycodone hydrochloride compositions or pharmaceutical formulations consisting of oxycodone hydrochloride, 8α, less than 100 ppm of 14-hydroxycodeinone, and a ratio of 8α to oxycodone hydrochloride of 0.04% or less.

94. McGinity was considered by the PTO Examiner in allowing the asserted claims of the Low 8α/ABUK patents.

7. *In re OxyContin Antitrust Litigation*

To the extent they are required to do so, Plaintiffs intend to prove the following fact:

95. The *In re OxyContin Antitrust Litigation* decision was considered by the PTO Examiner in allowing the asserted claims of the Low 8α/ABUK patents.

8. Objective Indicia

96. Whether objective indicia of non-obviousness such as commercial success, long-felt but unmet need, skepticism, unexpected results, copying, and failure of others, support the validity of the asserted claims of the Low 8α/ABUK patents.

97. Whether the inventions of the asserted claims of the Low 8α/ABUK patents fulfilled a long-felt but unmet need.

98. Whether, before the time of the inventions, others tried but failed to arrive at the inventions of the asserted claims of the Low 8α/ABUK patents.

99. Whether the inventions of the asserted claims of the Low 8α/ABUK patents were surprising.

100. Whether the inventions of the asserted claims of the Low 8α/ABUK patents achieve unexpected results.

101. Whether, at the time of the inventions, a POSA would have been skeptical that it was possible to arrive at the claimed inventions of the Low 8α/ABUK patents.

102. Whether the inventions of the asserted claims of the Low 8α/ABUK patents have been copied by others.

II. VALIDITY OF THE ABUSE-DETERRENT PATENTS-IN-SUIT

A. Claim Elements That Impart Structure

103. Whether Defendant must show that the following limitations of the asserted product-by-process claims of the Mannion ’933 and ’808 patents (the “process” limitations”) are satisfied for purposes of establishing invalidity based on prior art:

- Mannion ’933 patent claim 1[2] -- “the active agent and high molecular weight PEO are combined in a solid oral extended release dosage form that is (i) compression shaped, (ii) air cured by heated air, without compression, for at least about 5 minutes at a temperature above the softening temperature of the high molecular

[2] Claim 1 is no longer asserted but is incorporated into asserted dependent claims 3 and 8.

weight PEO, (iii) cooled, and (iv) hardened" (and related elements recited in dependent claims);

- '808 patent claim 1[3] -- "the active agent and high molecular weight PEO are combined in a solid oral extended release dosage form that is (i) compression shaped, (ii) air cured by heated air, without compression, for at least about 5 minutes at a temperature above the softening temperature of the high molecular weight PEO, (iii) cooled, and (iv) hardened" (and related elements recited in dependent claims); and
- '808 patent claim 11 -- "the active agent and high molecular weight PEO are combined in a solid oral extended release dosage form that is (i) compression shaped, (ii) air cured by heated air, without compression, for a curing time of at least about 10 minutes at a curing temperature of at least about 60 °C, (iii) cooled, and (iv) hardened".

104. Whether the process limitations impart structure to the asserted claims of the Abuse-Deterrent patents.

105. Whether the process limitations result in a decrease in density, as demonstrated by undisputed data, including data disclosed in the specification and prosecution history of the Abuse-Deterrent patents.

106. Whether the decrease in density was surprising and unexpected.

107. Whether the prior art disclosed that curing (i.e., heating, as understood by a POSA) resulted in an increase in density.

[3] Claim 1 is no longer asserted but is incorporated into asserted dependent claim 3.

B. Obviousness

108. Whether Defendant has proven by clear and convincing evidence that the asserted claims of the Abuse-Deterrent patents would have been obvious to a POSA at the time of the inventions based on the prior art, in particular, the combination of McGinity and the knowledge of those skilled in the art (Bartholomaus, Shao, Billa and Omelzuk).[4]

109. Whether Defendant has proven by clear and convincing evidence that, as of their priority date, the inventions of the asserted claims of the Abuse-Deterrent patents would have been obvious to a POSA, in light of the scope and content of the prior art, the differences between each claim at issue and the prior art, the level of ordinary skill at that time, and objective indicia of non-obviousness, in light of Defendant's above-identified prior art combination.

110. Whether Defendant has proven by clear and convincing evidence that its prior art combination discloses all of the elements of the corresponding asserted claims of the Abuse-Deterrent patents.

111. Whether the problem faced by a POSA would have been the same as that faced by the inventors, i.e., the abuse of Original OxyContin® and the development of a reformulation including Abuse-Deterrent properties.

112. Whether Defendant has proven by clear and convincing evidence that a POSA as of the priority date would have started with McGinity or any of Defendant's prior art when attempting to solve the problem faced by the inventors of the asserted claims of the Abuse-Deterrent patents.

[4] The asserted claims of the Abuse-Deterrent patents are: Mannion 933 patent claims 3 and 8; 808 patent claims 3 and 11; and 886 patent claims 6 and 12.

113. Whether a POSA would have started from scratch to develop a new extended-release oxycodone formulation.

114. Whether, instead, a POSA would have started with the Original OxyContin®, an extended-release oxycodone HCl formulation, and added Abuse-Deterrent properties to it.

115. Whether a POSA would have ignored the commercial and medical success of Original OxyContin® in selecting a starting formulation for the development of an Abuse-Deterrent, extended-release oxycodone formulation.

116. Whether a POSA would have ignored well-established Abuse-Deterrent technology, including the use of an antagonist.

117. Whether a POSA would have ignored prior art disclosing Abuse-Deterrent, extended-release oxycodone formulations.

118. Whether a POSA would have ignored prior art disclosing abuse-deterrent formulations of Original OxyContin®.

119. Whether a POSA would have started with McGinity when attempting to solve the problem faced by the inventors of the asserted claims of the Abuse-Deterrent patents.

120. Whether a POSA would have selected any of McGinity or Defendant's other prior art in formulating an abuse-deterrent formulation.

121. Even assuming a POSA would have selected and started with McGinity, would a POSA have modified or ignored its specific disclosures of working examples of crush-resistant tablets.

122. Even assuming a POSA would have selected and started with McGinity, would a POSA have modified or ignored its specific disclosures of working examples of crush-resistant tablets and instead developed the inventions of the asserted claims of the Abuse-Deterrent patents.

123. Even assuming a POSA would have sought to modify or ignore McGinity, would a POSA have turned to Bartholomaus.

124. Even assuming a POSA would have turned to Bartholomaus, would a POSA have modified or ignored its specific disclosures of working examples of abuse-deterrent tablets and instead developed the inventions of the asserted claims of the Abuse-Deterrent patents.

125. Even assuming a POSA would have sought to modify or ignore McGinity and Bartholomaus, would a POSA have turned to any of Shao, Billa or Omelczuk (the "oven" publications).

126. Even assuming a POSA would have sought to modify or ignore McGinity and Bartholomaus, would a POSA have sought to modify or ignore the teachings of the oven publications to achieve the inventions of the asserted claims of the Abuse-Deterrent patents.

127. Whether Defendant has proven by clear and convincing evidence that, at the time of the inventions of the asserted claims of the Abuse-Deterrent patents, a POSA would have had a motivation to combine particular teachings of the selected alleged prior art in a way that practices the inventions of the asserted claims of the Abuse-Deterrent patents.

128. Whether Defendant has proven by clear and convincing evidence that a POSA would have had a reasonable expectation of success of achieving the inventions of the asserted claims of the Abuse-Deterrent patents.

129. Whether the prior art as a whole taught a POSA away from the inventions of the asserted claims of the Abuse-Deterrent patents.

1. McGinity

To the extent they are required to do so, Plaintiffs intend to prove the following facts concerning McGinity:

130. McGinity is silent on abuse and abuse deterrence.

131. McGinity does not disclose any opioid. Analgesics such as aspirin, acetaminophen, diflunisal, and the like are non-steroidal anti-inflammatories that operate in a different fashion from opioids.

132. McGinity provides examples using only two drugs: chlorpheniramine maleate (CPM) and losoxanthrone. CPM is an approved antihistamine, and losoxanthrone is an experimental anti-cancer drug. McGinity does not disclose any examples containing opioids or any analgesics.

133. CPM, the API in McGinity examples 3 and 4, and oxycodone hydrochloride have very different structures. CPM is a salt of a weak acid (maleic acid) and chlorpheniramine, which is an N,N-dimethyl pyridinepropanamine. Oxycodone hydrochloride is the salt of a strong acid (hydrochloric acid) and the methylmorphinan-6-one backbone of the opioid. These two compounds have different molecular weights, melting points, and solubilities; these differences frequently affect interaction with polymers, such as PEO, and could readily lead to unpredictable release profiles.

134. McGinity states, "the particular combinations of therapeutic compound and PEO (of given molecular weight) will result in various formulations, each possessing a particular combination of properties." (McGinity 2:36-39.)

135. McGinity is directed to "formulations which have been prepared by hot-melt extrusion of mixtures containing high molecular weight PEO and a therapeutic compound" that are "controlled-released drug delivery preparations." (*Id.*at 1:13-17.) As the *In re OxyContin Antitrust Litig.*, found, "[a]t the heart of McGinity lies hot-melt extrusion." (994 F. Supp. 2d at 422-423.) Hot-melt extrusion was well known and available to a POSA.

136. McGinity does not disclose compositions or methods for preparing such composition involving "curing," as recited in the asserted claims of the Abuse-Deterrent patents. For example, McGinity does not disclose curing by: heated air; heated air after compression or heated air without compression.

137. McGinity does not disclose the curing conditions recited in the asserted claims of the Abuse-Deterrent patents. For example, a POSA would understand that McGinity heated for 2-3 minutes, not at least 5 or 10 minutes as recited in the asserted claims.

138. McGinity does not disclose pharmacokinetic, stability, or efficacy data for any formulation. In vitro data for another active ingredient cannot create a reasonable expectation of success of delivering effective amounts of oxycodone within the therapeutic range, irrespective of whether it would produce an abuse-deterrent formulation.

139. McGinity was considered by the PTO Examiner in allowing the asserted claims of the Abuse-Deterrent patents.

2. Bartholomaus

140. To the extent they are required to do so, Plaintiffs intend to prove the following facts concerning Bartolomaus:

141. Bartholomaus does not disclose, teach or suggest compositions or methods for preparing such compositions involving "curing," as recited in the asserted claims of the Abuse-Deterrent patents.

142. Bartholomaus does not disclose compositions or methods for preparing such compositions involving "curing," as recited in the asserted claims of the Abuse-Deterrent patents. For example, Bartholomaus does not disclose curing by: heated air; heated air after compression or heated air without compression. All of the examples in Bartolomaus disclose heating that is

simultaneous with compression.

143. Bartolomaus does not disclose the curing conditions recited in the asserted claims of the Abuse-Deterrent patents. For example, a POSA would understand that Bartholomaus discloses heating for 15 seconds, not at least 5 or 10 minutes as recited in the asserted claims.

144. Bartholomaus was considered by the PTO Examiner in allowing the asserted claims of the Abuse-Deterrent patents.

3. The Oven Publications

145. The oven publications are silent on abuse and abuse deterrence.

146. The oven publications do not disclose, teach or suggest any opioid.

147. The oven publications do not disclose, teach or suggest the use of PEO.

148. The oven publications do not disclose, teach or suggest a composition or method for preparing such composition involving "curing," as recited in the asserted claims of the Abuse-Deterrent patents.

149. The oven publications do not disclose, teach or suggest the curing conditions recited in the asserted claims of the Abuse-Deterrent patents. For example, the oven publications do not disclose, teach or suggest curing at or above the softening temperature or melting point of the disclosed polymers (none of which is PEO).

150. Even if a POSA ignored McGinity and Bartholomaus and selected a completely different curing process using an oven, Defendant will not prove by clear and convincing evidence that a POSA would have settled on the selected the specific conditions recited in the asserted claims of the Abuse-Deterrent patents.

151. Shao and Omelczuk were considered by the PTO Examiner in allowing the asserted claims of the Abuse-Deterrent patents.

4. Objective Indicia

152. Whether objective indicia of non-obviousness such as commercial success, long-felt but unmet need, skepticism, unexpected results, copying, and failure of others, support the validity of the asserted claims of the Abuse-Deterrent patents.

153. Whether OxyContin® has been a commercial success.

154. Whether there is a nexus between the commercial success of OxyContin® and the inventions of the asserted claims of the Abuse-Deterrent patents.

155. Whether the inventions of the asserted claims of the Abuse-Deterrent patents fulfilled a long-felt but unmet need.

156. Whether, before the time of the inventions, others tried but failed to arrive at the inventions of the asserted claims of the Abuse-Deterrent.

157. Whether the inventions of the asserted claims of the Abuse-Deterrent patents were surprising.

158. Whether the inventions of the asserted claims of the Abuse-Deterrent patents achieve unexpected results.

159. Whether, at the time of the inventions, a POSA would have been skeptical that it was possible to arrive at the claimed inventions of the Abuse-Deterrent patents.

160. Whether the inventions of the asserted claims of the Abuse-Deterrent patents have been copied by others.

III. REQUESTED RELIEF

161. Whether a judgment should be entered that the submission to the FDA of ANDA No. 213563 was an act of infringement of the patents-in-suit.

162. Whether a judgment should be entered that the commercial manufacture, use, sale,

offer for sale, or importation into the United States of the Accord's proposed ANDA products will infringe the patents-in-suit, particularly in view of Accord's stipulation of infringement.

163. Whether a judgment should be entered that Defendant will infringe and/or induce infringement of the patents-in-suit, particularly in view of Accord's stipulation of infringement.

164. Whether a judgment should be entered ordering that the approval date of Accord's proposed ANDA products be a date not earlier than the expiration of the patents-in-suit, plus any additional periods of exclusivity.

165. Whether a permanent injunction should be entered pursuant to 35 U.S.C. §§ 271(e)(4)(B) and/or 283 and/or Rule 65, Fed. R. Civ. P., against future infringement of the patents-in-suit through the commercial manufacture, use, sale, offer for sale, or importation into the United States of Accord's proposed ANDA products or any other product that infringes the patents-in-suit or the inducement of such activity, particularly in view of Accord's stipulation of infringement.

166. Whether this is an exceptional case within the meaning of 35 U.S.C. §§ 271(e)(4) and 285 warranting an award of reasonable attorneys' fees to Plaintiffs.

167. Whether Plaintiffs should be awarded fees and costs.